

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

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[Docket No. 01N-0249]

**Agency Information Collection Activities; Proposed Collection; Comment Request;  
Consumer and Producer Surveys on Economic Issues**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on proposed voluntary surveys of consumers and producers in order to help FDA comply with Executive Order 12866, the Regulatory Flexibility Act (RFA), and the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA).

**DATES:** Submit written or electronic comments on the collection of information by *[insert date 60 days after date of publication in the **Federal Register**]*.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1227.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

### **Consumer and Producer Surveys on Economic Issues**

Under section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)), FDA is authorized to conduct research relating to regulated articles and to collect information relating to responsibilities of the agency. Executive Order 12866, RFA, and SBREFA direct Federal agencies to conduct regulatory impact analysis, and to consider flexible regulatory approaches.

In order to perform the mandatory analysis it is often necessary to survey: (1) Regulated producers to determine existing practices and the changes in those practices likely under various policy options, (2) both consumers and manufacturers to explore attitudes towards policy proposals, and (3) industry experts to solicit expert opinions. FDA is seeking OMB clearance to conduct future surveys to implement Executive Order 12866, RFA, and SBREFA. Participation in the surveys will be voluntary. This request covers regulated entities, such as food processors, dietary supplement manufacturers, health professionals or other experts, and consumers.

FDA will use the information gathered from these surveys to identify current business practices, expert opinion, and consumer or manufacturer attitudes towards existing or proposed policy. FDA projects approximately 2 to 6 surveys per year, with a sample of between 10 and 1,000 respondents each for mail and telephone surveys, and a sample of up to 3,000 respondents for cable or internet surveys.

FDA estimates the upper bound burden of this collection of information as follows:

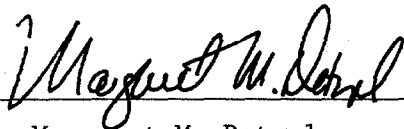
TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Type of Survey	No. of Respondents	Annual Frequency per Response	Hours per Response	Total Hours
Mail questionnaire .....	1,000	1	3	3,000
Phone survey .....	1,000	1	0.5	500
Internet or cable survey .....	3,000	1	1	3,000
Total .....				6,500

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

These estimates are based on the expected number of respondents necessary to obtain a statistically significant stratification of the average to large size industries—including small business entities covered by FDA regulations—and consumers of regulated products.

Dated: 6/8/01  
June 8, 2001.



Margaret M. Dotzel,  
Associate Commissioner for Policy.

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